540.1004CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Anand R. BAICHWAL, et al.
Serial Number:	10/047,060
Filed:	January 14, 2002
Entitled:	**CONTROLLED RELEASE INSUFFLATION CARRIER FOR MEDICAMENTS**
Examiner:	AZPURU, CARLOS, A (ART UNIT: 1615)

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

October 23, 2003

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

S I R:

Appellants submit this brief for the consideration of the Board of Patent Appeals and Interferences in support of their appeal of the Final Rejection dated February 26, 2003 in the above-identified application. A Notice of Appeal was filed on August 22, 2003 including a Petition for a three-month extension of time and the appropriate fees. An original and two copies of this brief are submitted herewith. The statutory fee under 37 C.F.R. § 1.17(c) of $330.00 is paid concurrently herewith.

I. REAL PARTY IN INTEREST

The real party in interest is Penwest Pharmaceuticals Co., a U.S. corporation having a place of business at 2981 Route 22, Patterson, N.Y. 12563,

USA, assignee of the entire right, title and interest in the above-identified patent application. The invention was assigned by the inventors Anand R. BAICHWAL and John N. STANIFORTH to Penwest Pharmaceuticals Co in June of 1995 during the prosecution of the parent application, now U.S. Patent No. 5,612,053, issued on March 18, 1997. The assignment was recorded on July 10, 1995 at reel 7543, frame 0885.

II. RELATED APPEALS AND INTERFERENCES

Appellants and their legal representatives and assignee are not aware of any appeal or interference that directly affects, will be directly affected by, or will have a bearing on the decision in this appeal.

III. STATUS OF THE CLAIMS

Original claims 1 – 25 were replaced by claims 26 – 42 via Preliminary Amendment dated January 14, 2002. Claim 43 was added in the Applicants' Response dated August 12, 2002.

Claims 26 - 43 are pending in this application. No claims have been allowed, all claims being subject to a final rejection dated on February 26, 2003, as narrowed by an Advisory Opinion dated August 14, 2003 (removing the rejection of claims 26 - 43 under 35 U.S.C § 112, first paragraph), and it is from this final rejection that this Appeal is taken. A copy of these appealed claims is attached hereto as Appendix A.

IV. STATUS OF AMENDMENTS

Appellants submit that no amendments have been filed subsequent to final rejection.

V. SUMMARY OF THE INVENTION

The present invention is designed to solve the particular problem in drug delivery to the respiratory system of a patient. Many drug treatment regimens

require a drug to be administered for period of time that is longer than the duration of effect of drug from a single dosage. Accordingly, multiple doses of drug must be delivered which is inconvenient for many patients. When scheduled doses are not administered, referred to as non-compliance, there is a disruption in drug therapy leading to ineffective treatment.

In one embodiment, the present invention provides a device for delivering a medicament to a patient, comprising a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum and a means for delivering the cohesive composite to a nasal or oral orafice. The average particle size of the cohesive composite particles is from about 0.1 to about 125 microns in diameter.

In another embodiment, the invention provides a device for delivering a medicament to a patient, comprising: 1) an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient; 2) a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier; and 3) an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port. The pharmaceutically acceptable carrier of this embodiment comprises xanthan gum and locust bean gum and the average particle size of the cohesive composite particles is from about 0.1 to about 125 microns in diameter

VI. ISSUES PRESENTED FOR APPEAL

The following two issues are presented for appeal:

(1) Whether claims 26 - 43 are unpatentable under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention; and

(2) Whether claims 26 - 43 are unpatentable under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,284,133 to Burns, et al., (the Burns patent) and under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,239,993 to Evans et al, (the Evans patent).

VII. GROUPING OF CLAIMS

The Examiner has rejected all of claims 26 - 43 as a single group. However, Appellants believe that these claims on appeal may be divided into two (2) groups for appeal of the 35 U.S.C. § 112, second paragraph rejection. As argued below, Appellants assert that these groups of claims are separately patentable for purposes of the 35 U.S.C. § 112, second paragraph rejection, and the claims of each group stand or fall together.

Group I includes claims 26 – 42.

Group II includes claim 43.

VIII. ARGUMENTS

A. Summary

Group II (claim 43) uses the statutorily authorized means plus function language to particularly point out and distinctly claim what Appellants regard as the invention in compliance with as required by 35 U.S.C. § 112, paragraphs two and six. Group 1 (claims 26 – 42) recites a device including an actuator a chamber and a pharmaceutical composition. There is no allegation that these limitations are unclear. Rather, the Examiner incorrectly contends that the composition limitations cannot be considered in a device claim, and that this somehow renders the claims indefinite.

As for the Examiner's rejection under 35 U.S.C. § 102 (b), the Examiner has refused to consider the composition limitations when rendering his rejection. Appellants explain that composition limitations must be considered when

evaluating patentability of a claimed device. When the present claims are compared to the cited prior art references, it is readily apparent that neither prior art reference discloses the novel pharmaceutical composition of the present invention. As the cited references fail to teach all of the limitations of the present claims, the Examiner's rejection of the claims under 35 U.S.C. § 102 (b) is improper.

B. Rejection Based Upon 35 U.S.C. § 112, second paragraph

The first issue presented is whether claims 23 - 46 are unpatentable under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Appellants submit that the Examiner's final rejection is in error and should be reversed.

1. The Examiner's Rejection

In the Final Office Action dated February 26, 2003, the Examiner rejected claims 26 - 43 under 35 U.S.C. § 112, second paragraph, stating that "the claims lack any device limitations which would particularly point out the claimed invention. Applicant is attempting to limit the device through the use of a claimed composition only. The claims are therefore indefinite in that they do not distinctly claim a device by any limitations other than those which comprise an output port, a chamber and an actuator. The composition limitations do not particularly point out the claimed device. Clarification is requested."

Also in the Final Office Action dated February 26, 2003, in response to the Appellants' arguments at pages 6-8, the Examiner stated that "Applicant also argues that the claims are directed to a device with a particular formulation contained therein. However applicant is reminded that the pharmaceutical formulation does not further limit the claimed device."

In the Advisory Action dated August 22, 2003, the Examiner stated that the request for reconsideration [of Appellants' Response dated July 28, 2003] has been considered but does not overcome the rejection(s) because it does not overcome the rejections of 35 U.S.C. § 112, second paragraph as well as 35 U.S.C. § 102 (b)."

2. The Examiner's Rejection under 35 U.S.C. § 112, second paragraph is improper

In his rejection, the Examiner does not allege that the elements of Group I (claims 26 – 42) or Group II (claim 43) are unclear. He instead objects that the "*composition limitations do not particularly point out the claimed device.*"

Group II

Independent claim 43 is a means plus function claim which recites:

> 43. A device for delivering a medicament to a patient, comprising a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> means for delivering the cohesive composite to a nasal or oral orafice.

35 U.S.C. § 112, sixth paragraph sets forth the statutory language for means plus function claims and states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

With respect to claim 43, the element in question is any one of the disclosed devices. This element is expressed as a means for performing a specified function (i.e., means for delivering the cohesive composite to a nasal or oral orafice). As statutorily authorized by 35 U.S.C. § 112, sixth paragraph, no recital of structure, material or acts in support of performing the function is given in the claim. The result of using this claim language and invoking 35 U.S.C. § 112, sixth paragraph is that the claim shall be construed to cover the

corresponding structure, material or acts described in the specification and equivalents thereof (i.e., the disclosed devices).

Thus, Appellants are statutorily authorized to claim their invention in the means plus function format set forth in claim 43. The composition and the disclosed devices are described in detail in the specification on pages 19 - 25. Moreover, commercially available operative devices including the Easyhaler™ and Cyclohaler™ are disclosed. Therefore, under 35 U.S.C. § 112, sixth paragraph, the invention of claim 43, including the claimed novel composition and the means for delivering the composition to the nasal or oral orafice (thoroughly described in the specification as well as numerous patents incorporated by reference in the present specification) incorporates statutorily authorized means plus function language. It cannot be indefinite.

As proof that the specification clearly describes the invention of claim 43, Appellants point out that exemplary medicament delivery devices are described in the specification at pages 19 - 25 and 27 - 29 of the present specification. For purposes of enablement, WO 92/00771, (hereinafter the '771 reference, disclosing the Bespak device), U.S. Patent No. 2,587,215 (hereinafter the '215 reference, disclosing the Priestly device) and U.S. Patent No. 4,274,403 (hereinafter the '403 reference, disclosing the Struve device), provide a more than adequate description of three examples of the disclosed devices. Indeed, the description is well beyond the Examiner's assertion of merely a basic output port, chamber and actuator. The relevant portions of the specification discussing the references that disclose three examples of the disclosed devices including the '771, '215 and '403 references which are incorporated by reference in Appellants' specification and discussed in its Amendment of January 30, 2003 and July 28, 2003 are set forth below. The Bespak device is discussed as follows:

> [o]ne such device is known as the Bespak device described in PCT publication WO 92/00771, hereby incorporated by reference, and available from Innovata Biomed Limited. The device described therein includes a storage chamber for storing a powdered drug to be administered and a metering member having metering cups in which individual doses of the powdered drug are placed. Air is inhaled through an inhalation passage at one end of the device and directed into contact with the metering cup that has been filled with the powdered drug. The metering cup is oriented upwardly open to face the air stream and to enable the powder to be released from the cup. Upon inhalation, the dose is mixed with the air flow and continues through the mouthpiece to be inhaled.
>
> The metering cups on the metering member are arranged on an outer frusto-conical wall so that each metering cup is positionable to be upwardly open and face the air flow during inhalation. The metering member rotates so that the metering cups move between a position in which the cup receives a dose of the powered drug from the storage chamber to a position in which the cup is exposed to the air flow. As one cup is exposed to the air flow, another cup is aligned with the storage chamber and is being filled with powder.
> After the dose is blown from the metering cup, and upon subsequent rotation of the metering member, the cup is wiped and cleaned by a wiping element to remove any undispersed powder and then dried via a moisture absorbent material.

The Bespak device is described in even greater detail in the '771 reference. Appellants specifically point to pages 3 - 13 and Figures 1 through 8b of the '771 reference. Appellants also point out that this device is clearly an inhalation device and that the "composition" contained therein is discussed in no greater detail than as "a substance in finely divided form" (page 3, line 16) or "a drug in the form of micronised powder" (page 8, line 28).

At page 21 of the specification, the Priestly device is detailed as follows:

> [a]nother device for delivery of inhalation powders is described in U.S. Pat. No. 2,587,215 (Priestly), hereby incorporated by reference. Priestly describes an inhaler having a storage chamber containing a powdered medicament, a mixing chamber and means to move a set dose of medicament from the storage chamber to the mixing chamber. The dose is mixed with air in the mixing chamber and inhaled through a mouthpiece.

In the '215 reference virtually the entire specification is devoted to description of this device, as are all sixteen Figures. The "composition" contained within this inhaler is described in no greater detail than "the powder carrying parts of this embodiment", (see column 5, line 48) or "the powder to be inhaled", (column 2, line 48).

At pages 21 - 22 of the present specification, the Struve device is specifically discussed as follows:

> [y]et another inhalation device suitable for delivering powdered inhalation drugs is described in U.S. Pat. No. 4,274,403 (Struve), hereby incorporated by reference. Struve describes an inhaler for administering a powdered drug nasally, which includes storage means for containing a quantity of the drug therein. The storage means includes a feed hole through which the powdered drug may be received from the storage means. The device further includes a dispensing head operatively coupled to the storage means for dispensing the powdered drug more nasally. The dispensing head of the Struve inhaler includes a nozzle, a body portion, a dispensing cylinder and a vent means. The nozzle is shaped to be received in the nasal passage of the user. The nozzle includes a dispensing passageway for dispensing the dose into the nasal cavity of patient.
>
> The body portion is located adjacent the nozzle and has a traverse bore therein. The traverse bore operatively connects the dispensing passageway in

> the nozzle with the feed hole leading to the drug storage means. The feed hole and the dispensing passageway are transversely offset relative to one another at the points where they enter the transverse bore.
>
> The dispensing cylinder includes a metering chamber. The metering chamber may be selectively aligned with either the feed hole or the dispensing passageway. The dispensing cylinder is slidably received in the transverse bore for movement between a first transverse position in which the metering chamber is aligned with the feed hole and a second transverse position in which the metering chamber is aligned with the dispensing passageway. In its first position, the metering chamber can be filled with a charge of the powdered drug when the inhaler is manipulated. In the second position, places the charge of the powdered drug into the dispensing passageway for inhalation by the user.
>
> The vent means is formed as part of the dispensing cylinder and is capable of venting the metering chamber to atmosphere only in the second position of the cylinder, i.e. when the powder disposed in the device such that it may be inhaled by the user.

In the '403 reference, the Struve device is set forth in six Figures and is described across the entire specification. In the '403 reference, the "composition" is "a powdered medication or drug". The '403 reference further states that "[t]he type of drug being administered is not important to the [Struve] invention and may comprise any drug which is desirably administered to the nasal passages" (column 2, lines 63 - 66).

The composition of the present invention is described in the specification at page 7, line 22 through page 19, line 25, and page 25, line 34 through page 27, line 24.

Finally, the specification describes the combination of the novel composition and any one of the disclosed devices at page 19, line 27 through page

20, line 6 and the combination of the novel composition and the commercially available Miat Cyclohaler™ in Example 4 beginning on page 27.

In view of pages 7 - 30 of the specification, one of ordinary skill would appreciate that claim 43 satisfies both requirements of 35 U.S.C. § 112, second paragraph. Therefore, Appellants request that the 35 U.S.C. § 112, second paragraph rejection of claim 43 in Group II be reversed.

Group I

Claim 26 and claims 27 – 42 were rejected under 35 U.S.C. § 112, second paragraph along with claim 43 of Group II. However, Appellants believe that these claims are separately patentable from those of Group II because these claims recite the claimed device limitations and do not invoke 35 U.S.C. § 112, sixth paragraph.

Independent claim 26 recites:

> 26. A device for delivering a medicament to a patient, comprising
> an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;
>
> a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
>
> an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

Claim 26 satisfies both requirements of 35 U.S.C. § 112, second paragraph. Claim 26 clearly sets forth the novel composition. It also clearly sets forth a device. Independent claim 26 and claims 27 - 42 which are dependent from claim 26 are clear and definite. As discussed above on pages 8 - 11, the claims particularly point out and distinctly define the metes and bounds of the

subject matter that will be protected by the patent grant as required by 35 U.S.C. § 112, second paragraph. Indeed, the Examiner himself has not in any way indicated that these claims are unclear. Rather, the Examiner merely complained that claim 26 includes a limitation (i.e. the composition) that the Examiner disagrees with. If the Examiner believes the claim to be overly broad, the proper place for his rejection is under 35 U.S.C. § 102(b).

As a proper rejection under 35 U.S.C. § 112, second paragraph has still not been set forth, Appellants request that the rejection of claims 26 – 42 also be reversed.

C. Rejection Based Upon 35 U.S.C. § 102 (b)

The second issue presented is whether claims 26 – 43 are unpatentable under 35 U.S.C. § 102 (b) as being anticipated by each of the cited prior art references. Appellants submit that the Examiner's final rejection is in error and should be reversed.

1. The Examiner's Rejection

In the Final Office Action dated February 26, 2003, the Examiner rejected claims 26 – 43 under U.S.C. § 102 (b) as being clearly anticipated by U.S. Patent No. 5,239,993 to Evans et al, (the Evans patent) and as being anticipated by U.S. Patent No. 5,284,133 to Burns, et al., (the Burns patent).

Referring to the Evans patent, the Examiner stated that "Evans, et al. disclose a device for delivering medicament to a patient comprising an output port, a chamber, and an actuator which propels the medicament through the output port (see Abstract; Figure 3; and claims)." The Examiner also stated that "composition limitations cannot be used to define the claimed device over the prior art. Further, the claims lack any device limitations. The instant claims clearly set out a device which is clearly anticipated by Evans, et al."

Referring to the Burns patent, the Examiner stated that "Burns, et al.

disclose a device which comprises an output port, an actuator, and a chamber, (see Figure 4A; col. 7, lines 40-62; and claims). The method of delivery is disclosed at col. 5, lines 47 et seq; and cols. 6-7. Composition limitations cannot be used to define the claimed device over the prior art. Further, the claims lack any device limitations. The claims are clearly anticipated by Burns, et al.

Also in the Final Office Action dated February 26, 2003, in response to Appellants' arguments at pages 6-8, the Examiner stated that "the pharmaceutical [stored in and delivered from the device] does not determine the patentability of the device" and that " applicant cannot use cannot use the pharmaceutical to define a device claim."

In the Advisory Action dated August 22, 2003, the Examiner stated that the request for reconsideration [of Appellants' Response dated July 28, 2003] has been considered but does not overcome the rejection(s) because it does not overcome the rejections of 35 U.S.C. § 112, second paragraph as well as 35 U.S.C. § 102 (b)."

2. The Examiner's Rejection under 35 U.S.C. § 102 (b) is incorrect

For the purposes of the Examiner's rejection of claims 26 – 43 under 35 U.S.C. § 102 (b), Appellants believe that the claims need not be separated into individual groups and therefore, will be discussed together.

The Examiner rejected claims 26 - 43 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,284,133 to Burns, et al., (the Burns patent) and under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,239,993 to Evans et al, (the Evans patent).

In response, Appelants note that a proper rejection under 35 U.S.C. § 102(b) requires that each and every limitation of a claim be found in a prior art reference. See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 U.S.P.Q.2D 1508, 1512 (Fed. Cir. 2001), In re Bond. 910 F. 2d 831, 832 (Fed.Cir.

1990); Lindeman Machinefabrik v. Am Hoist and Derrick. 730 F. 2d 1452, 1458 (Fed. Cir. 1984). Further, the Court of Customs and Patent Appeals in In re Bernhart held that "[i]*f the prior art does not show or suggest the improved element itself, it defies logical reasoning to say that the same prior art suggests the use of that improved element in a combination.*" In re Bernhart, 417 F. 2d. 1395, (1969) at 1402.

The Burns patent and the Evans patent each fail to teach hint or suggest

"*a device for delivering a medicament to a patient, comprising an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient; a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter; an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port*" as recited in claim 26; or

"*a device for delivering a medicament to a patient, comprising a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter; means for delivering the cohesive composite to a nasal or oral orafice*" as recited in claim 43.

As such claims 26 and 43 are not anticipated under 35 U.S.C. § 102 (b). Dependent claims 27 - 42 are also not anticipated.

The Examiner has obsessively held on to his view that the composition is not a limitation of either means plus function claim 43 or claim 26. Yet, he still cites no support for this contention. In contrast, Appellants have cited case law and even issued patents (see U.S. Patent Nos. 6,030,642 and 5,597,582 discussed

below) which show that composition limitations can indeed distinguish the claimed device over the prior art.

Moreover, courts have repeatedly held that a single novel feature added to a known combination is patentable. The Federal Circuit has rejected and found untenable under current patent laws, the holding in Lincoln Engineering Co. v. Stewart, 303 U.S. 545 (1938), that "*the improvement of one part of an old combination gives no right to claim that improvement in combination with other old parts which perform no new function in the combination*". See e.g. Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d 840, (Fed. Cir. 1984) at 845; In re Bernhart, 417 F. 2d. 1395, 1402 (C.C.P.A. 1969) at 1403; and See also M.P.E.P. at § 2173.05(j).

The Examiner is respectfully reminded that the decision in Diamond v. Diehr, 450 U.S. 181 (1981) at 187, held that a prior art machine that performed a new algorithm was considered patentable. This is a clear example of how the element of a claim (i.e., the performed algorithm) which distinguishes the claimed invention from the prior art "thing" (i.e. the computer) need not be merely an improvement of the "thing" itself. This United States Supreme Court decision requires that all limitations of a claim "*must be considered as a whole*", and that "*[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.*" Diamond v. Diehr, at 188. Indeed, even limitations that are not statutory subject matter under 35 U.S.C. § 101 must be considered for purposes of a prior art rejection. Nevertheless, the Examiner failed to even mention this decision in his final Office Action. Although the Diamond v. Diehr decision was directed to patentable subject matter under 35 U.S.C. § 101, the reasoning in Diamond v. Diehr is applicable to other issues of patentability, including 35 U.S.C. § 102. The court in In re Bernhart also addressed a similar issue with respect to a claim directed to a prior art machine performing a novel algorithm as follows:

> 19. A system for providing a drawing of an object comprising in combination: electronic digital computer means programmed to respond to applied signals (x(e), y(e), z(e)) and a series of groups of signals (x(i), y(i), z(i)) to provide a corresponding series of pairs of output signals (v(i), w(i)) with the relationship between signals (x(i), y(i), z(i)) and (x(e), y(e), z(e)) to the signals (v(i), w(i)) being defined as follows:
>
> [Graphic omitted. See illustration in original.]
>
> where k is a selectable variable; signal means coupled with said computer means and providing said signals (x(i), y(i), z(i)) and (x(e), y(e), z(e)) thereto with said signals (x(i), y(i), z(i)) representing the three dimensional co-ordinates of selected points on the object and with said signals (x(e), y(e), z(e)) representing the three dimensional co-ordinates of the location of the observation point from which the object is seen; and planar plotting means coupled with said computer means and responsive to said signals (v(i), w(i)) to make a drawing of the object.

holding that ". . . *we note that the only apparatus recited is the admittedly old computer and plotting machine and the sole distinction presented therein upon which patentability could be predicted is the identification in the claims of the meaning which certain signals represent to the human mind, or the algorithm which the computer is to solve.*" *Emphasis added.* In re Bernhart, 417 F. 2d. 1395, (1969) at 1398. Similarly, the novel element of the present claims, (i.e. the pharmaceutical formulation) is also the feature that distinguishes the invention from the prior art "thing" (i.e. the device). Although the novel formulation is not an improvement of the device itself, it must be considered in a patentability analysis.

The Examiner argues that the improvements described in Appellants' cited cases Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d. 840, (Fed. Cir. 1984) at 845 and In re Bernhart, 417 F.2d. 1395, (1969) at 1403; and M.P.E.P., 8th Ed., at 2173.05(j) are *"a further limitation of what was being claimed."* This point is irrelevant. The above mentioned case law holds that all limitations of a claim must be considered. Once again, the Examiner has cited no authority whatsoever to justify ignoring express limitations of the present claims.

Moreover, it is clear from the decisions in In re Bernhart, Diamond v. Diehr and Radio Steel that all claim limitations, even including elements that are not, in and of themselves novel or even statutory subject matter, must be considered for patentability.

In further support of the fact that a device can be limited by a composition stored within the device, Appellants submit that there are innumerable patents which claim a prior art object (e.g. a device or capsule), wherein the novel feature is a composition stored therein. For example:

Claim 1 of United States Patent No. 6,030,642 recites:

> 1. An oral pharmaceutical dosage unit formulation for the extended release of clonidine to effect central alpha-adrenergic stimulation over a prolonged period upon administration thereof, wherein the oral dosage unit is a gelatin capsule containing a homogeneous powder mixture, the homogenous mixture consisting essentially of:
>
> a. from about 0.025 mg. to about 0.40 mg. clonidine for the treatment of attention deficit hyperactivity disorder;
>
> b. from about 30 to about 70 percent by weight of a high molecular weight, high viscosity cellulose ether; and
>
> c. a therapeutically inert, pharmaceutically acceptable adjunct material, wherein the release period is from about 8 to about 12 hours. *Emphasis added.*

Further, United States Patent No. 5,597,582, issued on January 28, 1997 claims:

> 1. A gelatin capsule comprising a gelatin shell having enclosed therein based on the total weight of content of from about 200 to about 2000 mg: of from about 5 to about 50% w/w of an anticancer compound of the formula ##STR3## wherein X is H; hydrocarbyl (1-4C); hydrocarbyl (1-4C) substituted with OH, NH.sub.2, NHR or NRR; halogen; OH; alkoxy (1-4C); NH.sub.2 ; NHR or NRR; wherein each R is independently selected from lower alkyl (1-4C) and lower acyl (1-4C) and lower alkyl (1-4C) and lower acyl (1-4C) substituted with OH, NH.sub.2, alkyl (1-4C) secondary and dialkyl (1-4C) tertiary amino groups, alkoxy (1-4C) or halogen; and when X is NRR, both R's taken together directly or through a bridge oxygen to form a morpholino ring, pyrrolidino ring or piperidino ring;
>
> n is 0 or 1; and

> Y.sup.1 and Y.sup.2 are independently either H; nitro; halogen; hydrocarbyl (1-14C) including cyclic and unsaturated hydrocarbyl, optionally substituted with 1 or 2 substituents selected from the group consisting of halogen, hydroxy, epoxy, alkoxy (1-4C), alkylthio (1-4C), primary amino (NH.sub.2), alkyl (1-4C) secondary amino, dialkyl (1-4C) tertiary amino, dialkyl (1-4C) tertiary amino where the two alkyls are linked together to produce a morpholino, pyrrolidino or piperidino, acyloxy (1-4C), acylamido (1-4C) and thio analogs thereof, acetylaminoalkyl (1-4C), carboxy, alkoxycarbonyl (1-4C), carbamyl, alkylcarbamyl (1-4C), alkylsulfonyl (1-4C) or alkylphosphonyl (1-4C), wherein the hydrocarbyl can optionally be interrupted by a single ether (--O--) linkage; or wherein Y.sup.1 and Y.sup.2 are independently either morpholino, pyrrolidino, piperidino, NH.sub.2, NHR', NR'R'O(CO)R', NH(CO)R', O(SO)R', or O(POR')R' in which R' is a hydrocarbyl (1-4C) which may be substituted with OH, NH.sub.2, alkyl (1-4C) secondary amino, dialkyl (1-4C) tertiary amino, morpholino, pyrrolidino, piperidino, alkoxy (1-4C), or halogen substituents, or pharmacologically acceptable salt of said compound;
>
> of from about 50 to about 95% w/w of an oily excipient selected from the group consisting of soybean oil and fractionated coconut oil;
>
> of from about 0 to about 30% w/w of viscosity modifier; and
>
> of from about 0 to about 10% w/w of a pharmaceutically acceptable surface active agent. *Emphasis added.*

Both of these claims were issued by the United States Patent and Trademark Office. Both of these claims also recite inventions directed to novel compositions stored within a prior art capsule. Just as a prior art gelatin capsule in combination with a novel formulation is patentable and a prior art jar in combination with a novel peanut butter composition is patentable; a claim reciting the combination of a prior art device in combination with a novel formulation must also be patentable. The Examiner is simply wrong on this issue.

Appellants further note that numerous claims have issued which recite a novel pharmaceutical formulation in a prior art carrier. In the chemical arts, this scenario can readily be illustrated by a novel dosage form that contains a claim element directed to a novel formulation contained within a prior art gelatin capsule. Applying the Examiner's reasoning to this example:

A formulation stored and administered in a known capsule cannot be used to define the dosage form. Therefore, the dosage form, containing a novel formulation and a known gelatin capsule would be unpatentable.

Clearly, this reasoning provides a result that is incorrect. When determining patentability, it would be incorrect to ignore claim limitations directed to the formulation simply because the carrier capsule is not novel.

The Examiner correctly points out that in the present application, Appellants are further limiting a device through the use of pharmaceutical limitations. As the pharmaceutical limitations are proper limitations in the claims and as these limitations are not found in the cited prior art, the claims of the present invention cannot be anticipated by the cited references. Just as a novel algorithm is to a prior art computer and a novel formulation is to a prior art capsule, so is the present novel composition to the prior art device.

Therefore, Appellants submit that the Examiner's rejection of claims 26-43 under 35 U.S.C. § 102 (b) be reversed.

IX. CONCLUSION

Appellants' claimed devices are properly limited by both device and compostion limitations. Claim 43 is a proper, statutorily authorized means plus function claim under 35 U.S.C. § 112, sixth paragraph and it, along with claims 26 -42 define the claimed invention with sufficient particularity to satisfy the requirements under 35 U.S.C. § 112, second paragraph. The claimed devices have limitations that are not disclosed or even suggested in the cited prior art, and Appellants believe that for the foregoing reasons the final rejections of claims 260-043 must be reversed.

Prompt consideration of the arguments presented herein and reversal of the final rejections is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Leslye B. Davidson
Reg. No. 38,854

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, NY 10018
Tel: (212) 736-1940

APPENDIX A

PENDING CLAIMS 26 - 43
OF U.S. PATENT APPLICATION NO. 10/047,060

26. A device for delivering a medicament to a patient, comprising

an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;

a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;

an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

27. The device of claim 26, wherein said pharmaceutically acceptable carrier comprises said xanthan gum and said locust bean gum in a ratio of from about 1:3 to about 3:1.

28. The device of claim 26, wherein the average particle size of said cohesive composite particle is from about 0.1 to about 10 microns.

29. The device of claim 26, wherein the average particle size of said cohesive composite particle is from about 10 to about 125 microns.

30. The device of claim 26, wherein the medicament to gum ratio is from about 0.5:100 to about 1:1.

31. The device of claim 30, wherein the medicament to gum ratio is from about 1:100 to about 1:2.

32. The device of claim 26, further comprising from about 0.1 to about 50% by weight of a cationic cross-linking agent comprising an alkaline metal or an alkaline earth metal sulfate, chloride, borate, bromide, citrate, acetate or lactate.

33. The device of claim 32, wherein said cationic cross-linking agent is present in an amount of from about 1 to about 10% by weight.

34. The device of claim 32, wherein said cationic cross-linking agent is selected from the group consisting of potassium chloride and sodium chloride.

35. The device of claim 26, wherein said pharmaceutically acceptable carrier further comprises an inert saccharide diluent selected from the group consisting of monosaccharides, disaccharides and mixtures thereof.

36. The device of claim 35, wherein said inert saccharide diluent is selected from the group consisting of dextrose, sucrose, galactose, lactose and mixtures thereof.

37. The device of claim 26, wherein said pharmaceutically acceptable carrier further comprises a pharmaceutically-acceptable surfactant in an amount of from about 0.5 to about 3% by weight of the controlled release carrier.

38. The device of claim 37, wherein said surfactant is selected from the group consisting of pharmaceutically-acceptable anionic surfactants, cationic surfactants, amphoteric (amphipathic/amphophilic) surfactants, non-ionic surfactants, and mixtures thereof.

39. The device of claim 26, wherein said controlled release particles are compressed together to form a solid mass.

40. The device of claim 26, wherein said controlled release pharmaceutical is suitable for delivery to the upper respiratory tract of a human patient.

41. The device of claim 26, wherein said controlled release pharmaceutical is suitable for oral insufflation therapy.

42. The device of claim 26, wherein said cohesive composite is in the form of a granulate.

43. A device for delivering a medicament to a patient, comprising

a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;

means for delivering the cohesive composite to a nasal or oral orafice.